In the Office Action, the Examiner has rejected claims 1-20 under 35 U.S.C. §103(a) as being unpatentable over Lalonde et al. (U.S. Patent No. 6,283,959) in view of Benson (U.S. Patent No. 4,082,096), Dobak, III (U.S. Patent No. 6,482,226), and Kudaravalli et al. (U.S. Patent No. 6,471,694).

In response to the Office Action, independent claims 1, 8 and 15 have been amended to require a shapeable rod to selectively establish a configuration for the enclosure to conform the enclosure to the exposed tissue. Further, independent claims 1, 8 and 15 have been amended to now recite a device (claims 1 and 8) and method (claim 15) for cryoablating tissue that includes a pathway between the outlet of the capillary tube or flow-restricting device to the enclosure that is unimpeded by the rod. To be consistent with these amendments, claims 5, 11, 12 and 19 have been amended to comply with the independent claims from which they depend. Further, claim 21 has been added. Support for these amendments can be found in the specification on page 4, lines 18-22, page 8, lines 7 to 22, and Figs. 2 and 3.

Amendments to the claims have been presented herein to point out the features which distinguish the present invention over the cited art. Claims 1-3, 5-9 and 11-21 are now pending.

Rejections under 35 U.S.C. § 103(a)

In the Office Action, claims 1-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lalonde et al. (U.S. Patent No. 6,283,959) in view of Benson (U.S. Patent No. 4,082,096), Dobak, III (U.S. Patent No. 6,482,226), and Kudaravalli et al. (U.S. Patent No. 6,471,694). In response, independent claims 1, 8 and 15 have been amended in at least two important respects. Firstly, as indicated above, these claims now require a shapeable rod to selectively establish a configuration for the enclosure to conform the enclosure to the exposed tissue. Secondly, these claims also require that a pathway, that is unimpeded by the rod, exists between the outlet of the capillary tube or flow-restricting device and the enclosure. None of the cited references, individually or in combination, teach or suggest such a structure or cooperation of structure.

With regard to the claim limitation for the present invention, to the effect that the device includes a shapeable rod attached to the distal end of the shaft, such an element is not disclosed by any of the cited references, for the purposes now recited in the claims of the present invention. Instead of such a rod, Lalonde et al. disclose an endovascular catheter with a balloon that is effectively limited to two cryochamber configurations. These are a balloon deflated configuration and a balloon inflated configuration (see Lalonde et al. col. 2, lines 43-51). It is important to note that Lalonde et al. do not teach or suggest any structure that shapes the balloon to conform it to

Commissioner for Patents Serial No. 10/646,486 Page 11

exposed tissue. Further, with specific regard to the Dobak, III reference, reconfigurations of the device disclosed in this reference rely on changes in temperature (see Dobak, III col. 6, lines 49-54). In contrast, the shapeable rod in the presently claimed invention is manually reconfigured to conform to the shape of the exposed tissue. At Col. 7, line 27, Benson discloses the use of a "relatively rigid" rod. As shown in Fig. 3, the Benson rod (17) is not attached to the distal end of the shaft (11). Further, the porous mass (12) of Benson cannot be said to form a rod, nor is it disclosed as being attached to the distal end of the shaft. Further, Kudaravalli et al. includes no disclosure regarding any shapeable element.

With regard to the unimpeded pathway between the outlet of the capillary tube or flow-restricting device and the enclosure, none of the cited references discloses this combination of structure. Because the Office Action admits that only Benson could arguably be interpreted as disclosing a shapeable rod-shaped element, it is the only reference addressed here. As is clearly disclosed, Benson requires use of a mass of porous material through which the liquid cryogen is passed. As a result, passage of the cryogen is necessarily impeded by the porous material. The present invention, on the other hand, requires a pathway between the delivery point of the cryo-fluid and the enclosure which is unimpeded. Because it utilizes a shapeable rod, rather than a porous mass, the Applicant's invention is able to provide such an unimpeded pathway. Unlike the present invention, none of the cited references provide an unimpeded pathway for the cryo-fluid.

In light of the above arguments, Applicant respectfully contends that amended

claims 1, 8 and 15 are nonobvious with respect to the cited combination of references.

Further, since claims 2, 3, 5-7, 9, 11-14, and 19-21 depend directly or indirectly from

amended independent claims 1, 8 and 15, they are also nonobvious with respect to the

cited combination of references.

For the reasons set forth above, Applicant believes the basis for rejecting claims

under 35 U.S.C. § 103(a) has been overcome, and the rejections should, therefore, be

withdrawn. In conclusion, Applicant respectfully asserts that claims 1-3, 5-9 and 11-21

are patentable for the reasons set forth above, and that the application is now in a

condition for allowance. Accordingly, an early notice of allowance is respectfully

requested. The Examiner is requested to call the undersigned at 619-688-1300 for any

reason that would advance the instant application to issue.

Respectfully submitted,

NELL K. NYDEGGER
Attorney for Applicant

Registration No. 30,202

NYDEGGER & ASSOCIATES

348 Olive Street

San Diego, California 92103

Telephone: (619) 688-1300